

# Year in Review – 2011 Objectives & Budget Overview 2012

October 31 - November 2, 2011



PUBLICLY FILED PER STIPULATION [ECF 2140]

# Contents



- Clinical Development
  - Regulatory landscape and strategy
  - Epidemiology data review
  - Measures to ensure success



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In support of the public health, our near term goal is to provide data that will drive FDA to conclude that the original formulation was removed for safety considerations.



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# Epidemiologic studies – Post-Marketing Requirement

Studies	Routes	Usage/ demand	Addiction	Overdose	Death
NAVIPPRO - Substance Abuse Treatment Centers	✓	✓			
Kaiser Permanente – Overdoses among insured members				✓	✓
RADARS–Poison Centers	✓			✓	✓
National Surveys – RADARS College Survey, NSDUH	✓	✓	✓		
RADARS– Drug Diversion Program		✓			
Prescription Monitoring Programs - Doctor-shopping patients		✓			

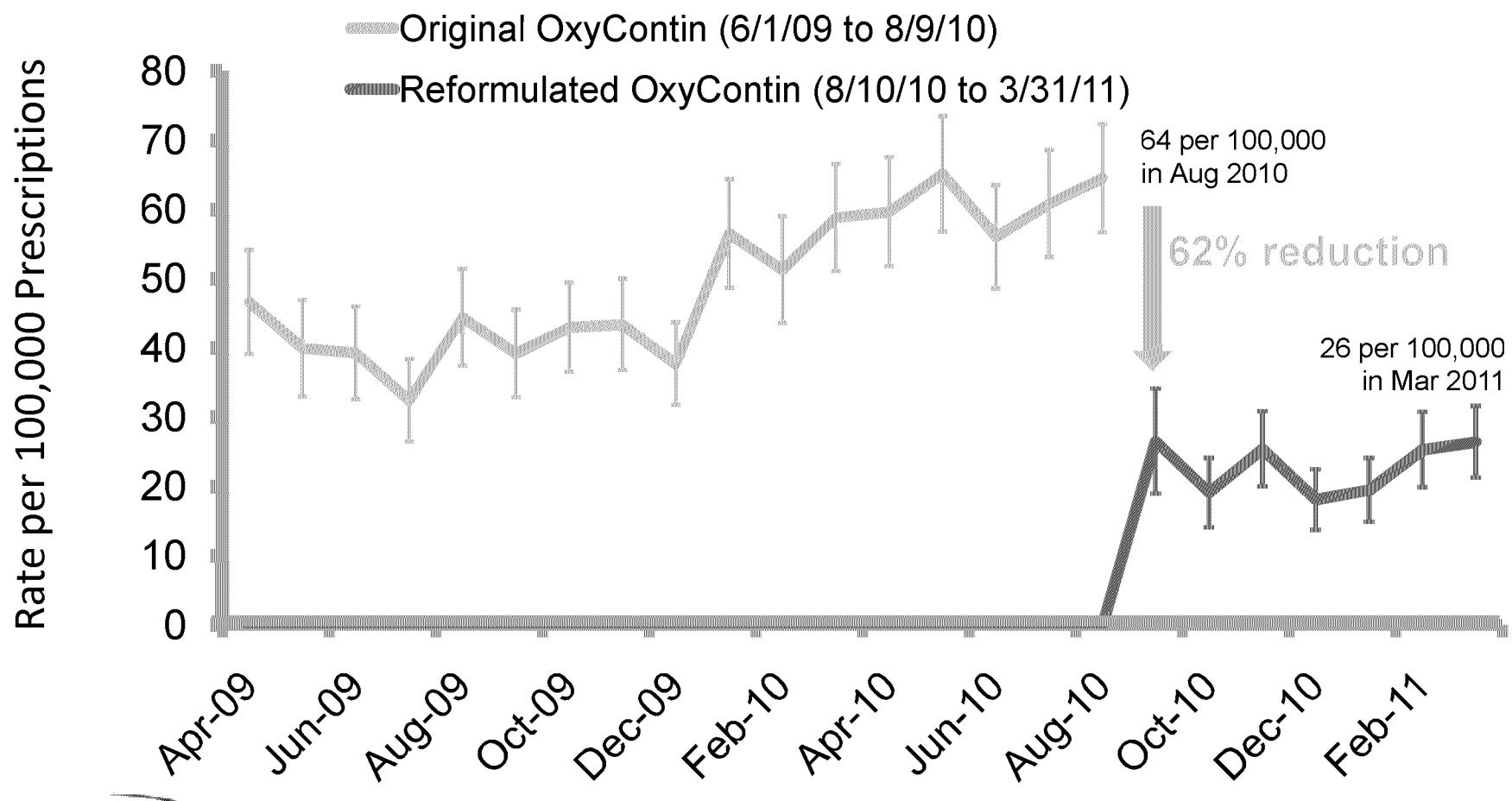


# Epidemiologic studies - Supplemental

Studies	Routes	Usage/ demand	Addiction	Overdose	Death
Internet monitoring for tamper recipes and abuse	✓	✓			
Abuser cohort in Kentucky	✓	✓	✓		
IMS prescription data – national and “region” 0 TRx		✓			
National poison data system – Poison Centers	✓			✓	✓
Purdue Adverse Event data base				✓	✓
State Medical Examiners Database					✓



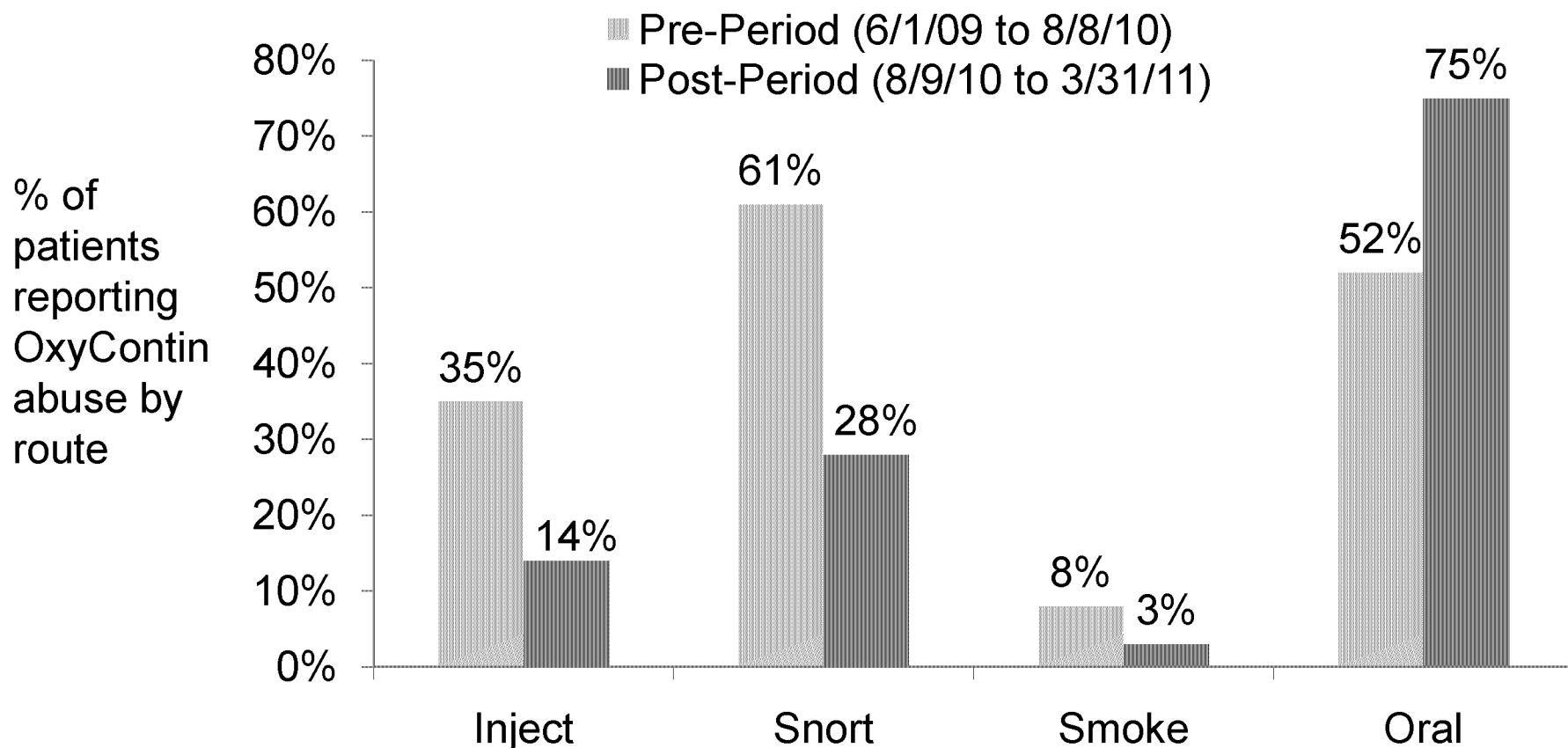
The rate of OxyContin abuse in patients admitted to participating substance abuse treatment centers has declined by 62%



Source: NAVIPRRO substance abuse treatment center surveillance

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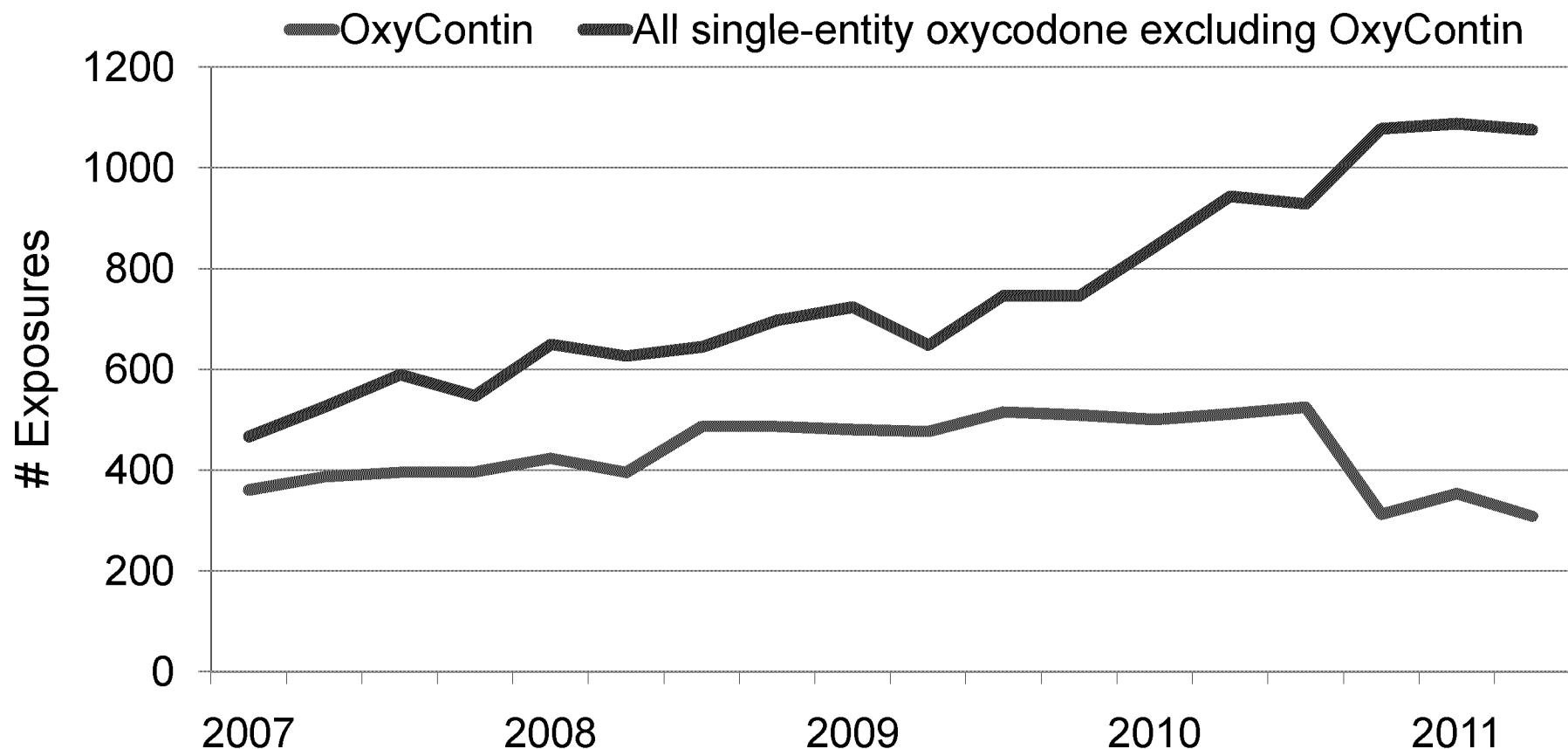
Among those who reported OxyContin abuse, injecting, snorting and smoking have declined substantially



Source: NAVIPRRO substance abuse treatment center surveillance

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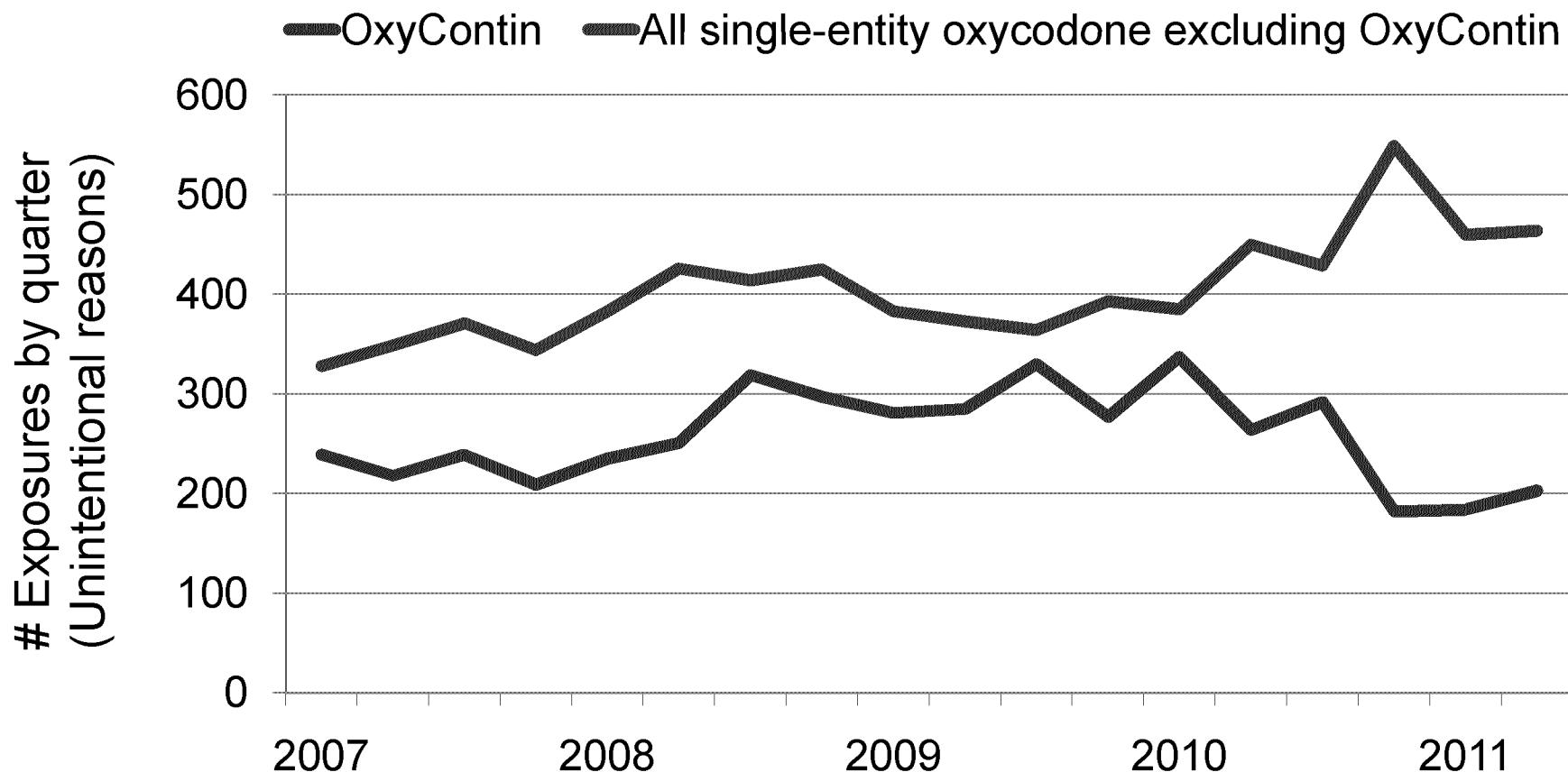
Intentional exposures reported through Poison Control Centers have declined for OxyContin and risen for single-entity oxycodone products (excluding OxyContin)



Source: US Poison Control Center Data

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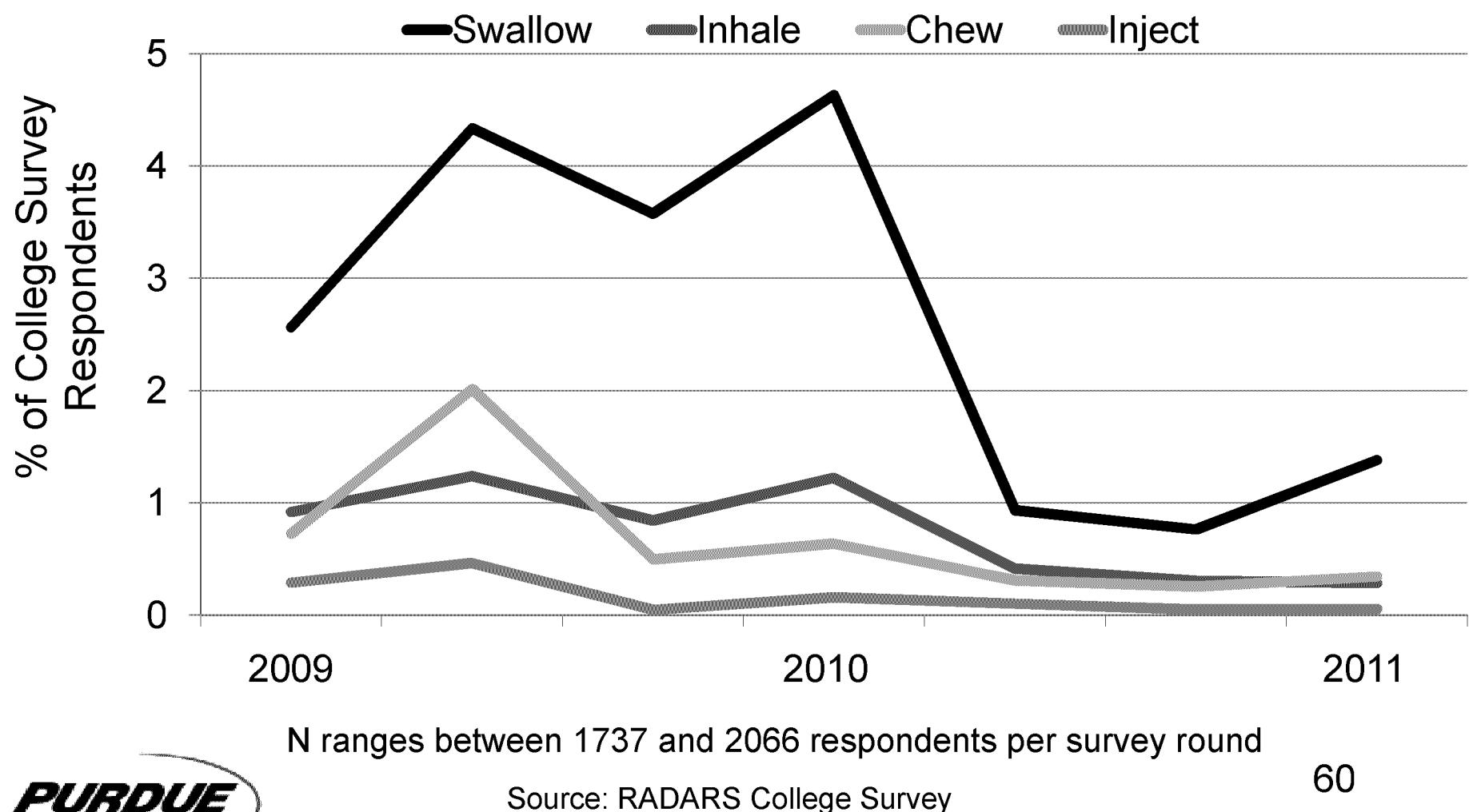
Unintentional exposures reported through Poison Control Centers have declined for OxyContin and risen for single-entity oxycodone products (excluding OxyContin)



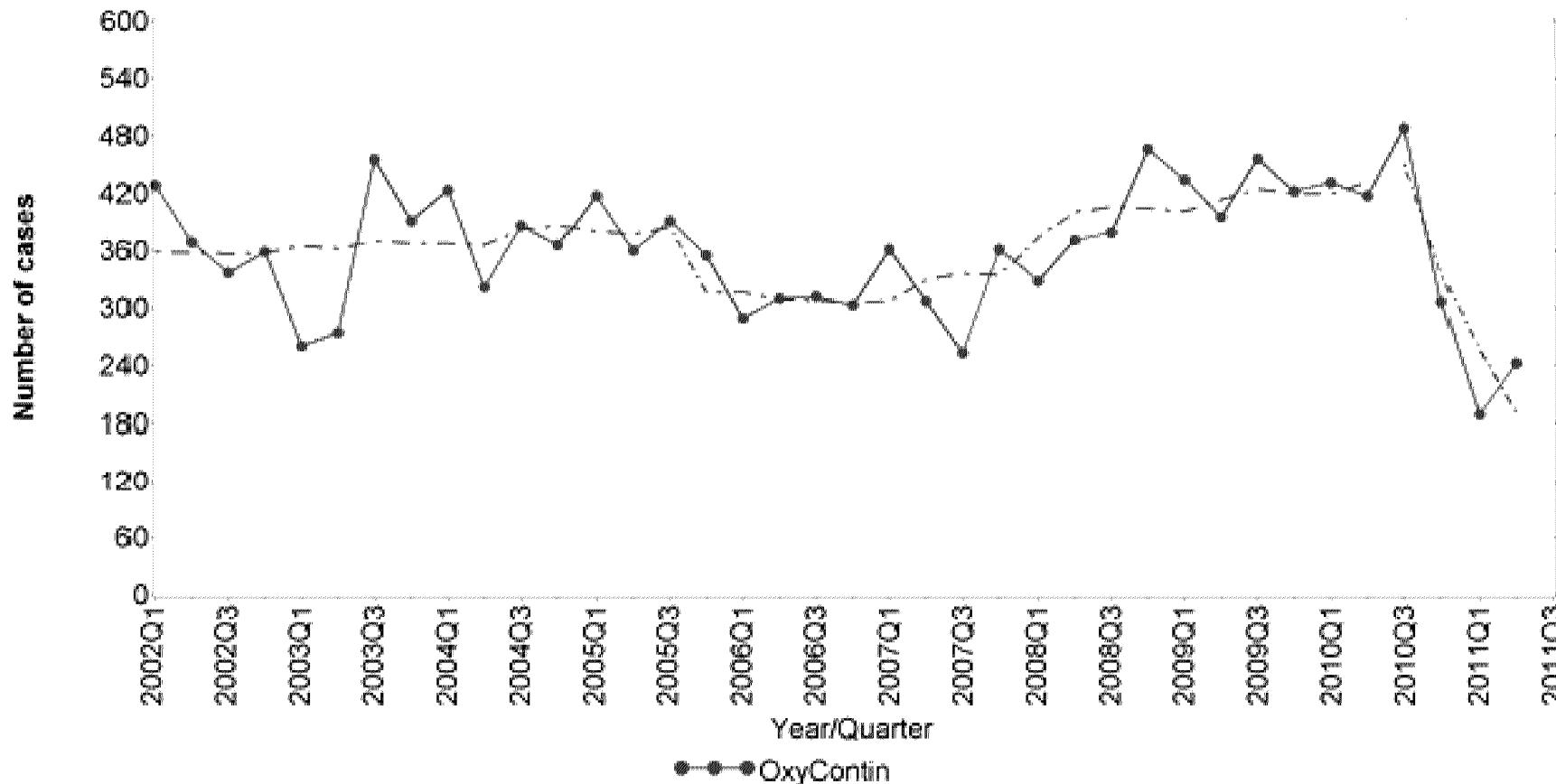
Source: US Poison Control Center Data

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Among college students the prevalence of OxyContin abuse has declined



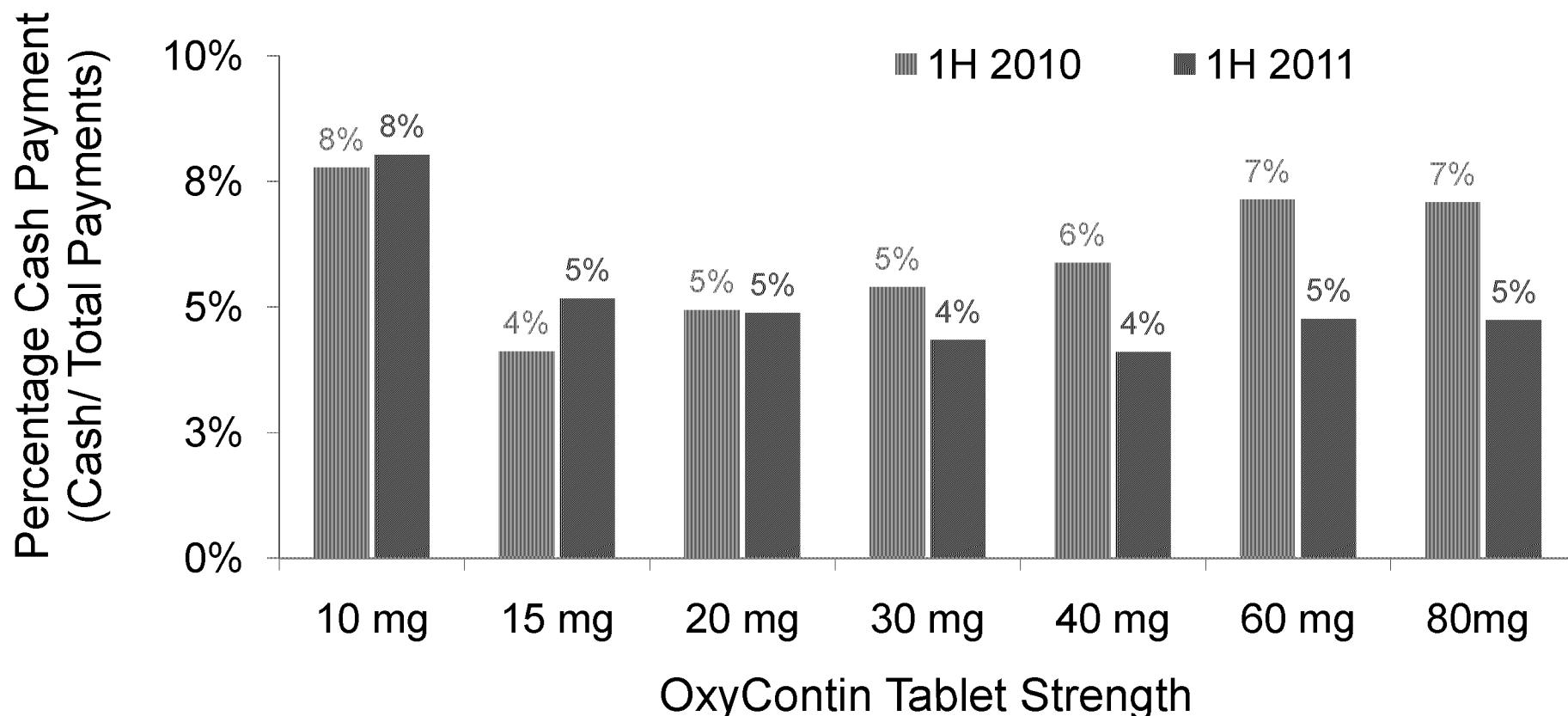
# Drug diversion cases have declined by nearly 50%



Source: The RADARS System Drug Diversion Program

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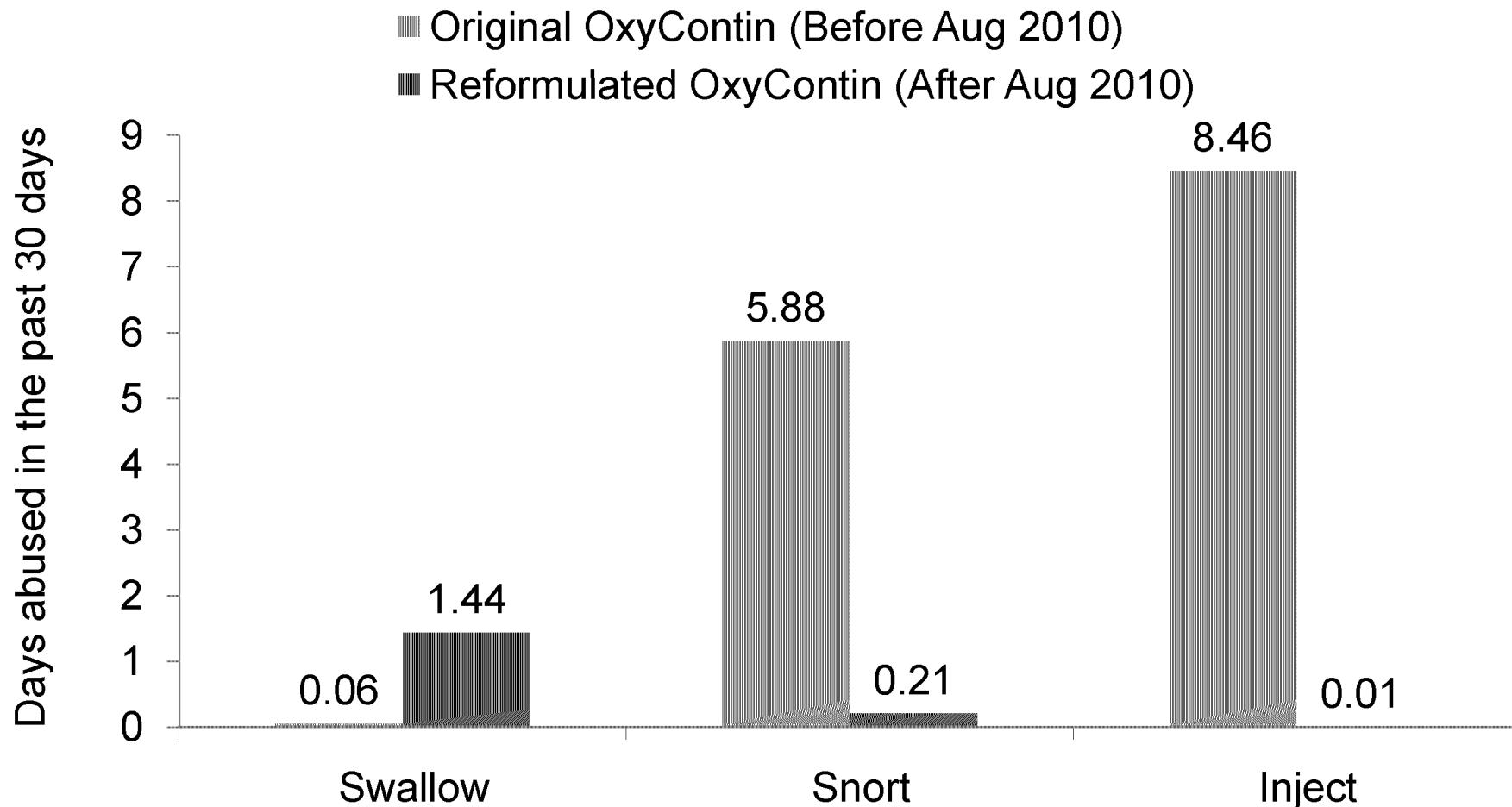
The percent of OxyContin Rxs paid for with cash has declined disproportionately for the higher strengths



Source: Ohio Prescription Monitoring Program

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# Snorting and injection of reformulated OxyContin is substantially lower in opioid abusers (n=192)



Source: University of Kentucky Study

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# Drug-abuse related adverse events have declined by more than 50%

Original "OC"  
Jan 1 – Aug 1 2010

Reformulated "OP"  
Jan 1 – Aug 1 2011

Preferred Term (MedDRA SMQ for Drug Abuse)	No. of OC cases	No. of OC cases / 100,000 Rx*	No. of ORF cases	No. of ORF cases / 100,000 Rx*
Accidental overdose	21	0.53	10	0.27
Dependence	4	0.10	0	0.00
Disturbance in social behaviour	1	0.03	1	0.03
Drug abuse	429	10.89	147	3.99
Drug abuser	13	0.33	3	0.08
Drug dependence	387	9.82	133	3.61
Drug dependence, antepartum	0	0.00	2	0.05
Drug detoxification	6	0.15	2	0.05
Drug level increased	10	0.25	1	0.03
Drug screen positive	1	0.03	2	0.05
Drug tolerance	17	0.43	6	0.16
Drug tolerance decreased	3	0.08	1	0.03
Intentional overdose	7	0.18	8	0.22
Multiple drug overdose	44	1.12	14	0.38
Multiple drug overdose accidental	25	0.63	12	0.33
Multiple drug overdose intentional	5	0.13	3	0.08
Overdose	94	2.39	33	0.90
Polysubstance dependence	5	0.13	5	0.14
Substance abuse	149	3.78	69	1.87
<b>Total</b>	<b>1,221</b>	<b>30.98</b>	<b>452</b>	<b>12.27</b>

Rate per 100,000 prescriptions during corresponding reporting interval

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**PURDUE**

# Provisional epidemiology study conclusions support our OxyContin strategy

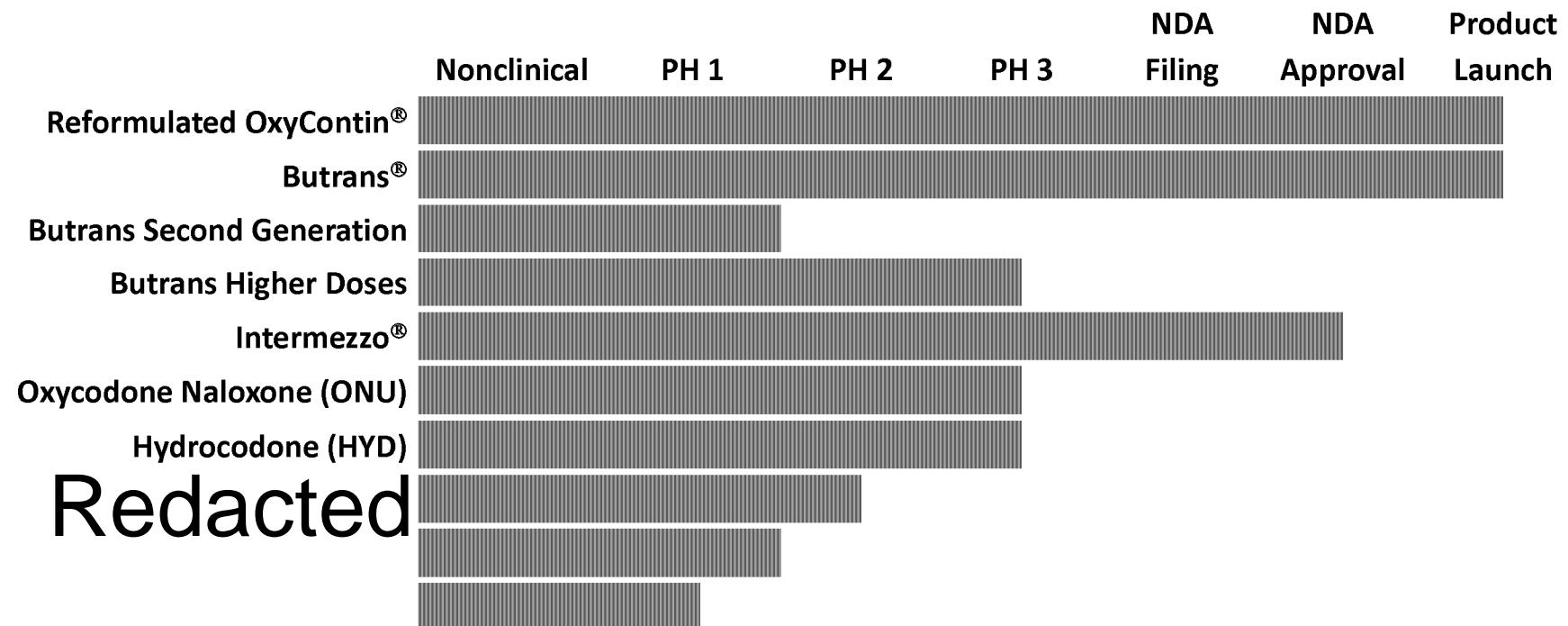
- Substantial reductions in OxyContin abuse following marketplace transition
- Substantial reduction in abuse via routes that require tampering
- Substantial reduction in adverse consequences of abuse

*Reformulated OxyContin offers significant tamper resistance, abuse deterrence, and on this basis, provides a meaningful public health benefit*



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These conclusions also support Purdue's long-term strategy and justify investment in our analgesic pipeline



# Ongoing and Planned Clinical Programs are the Largest Undertaking in Purdue's History



The primary resource and cost drivers are large, multinational, Phase III studies

	2009	2010	2011-2012
<b>Phase 1</b>	10	12	<b>26</b>
<b>Phase 2</b>	0	0	<b>4</b>
<b>Phase 3</b>	2	1	<b>12</b>
<b>US Sites</b>	121	18	<b>863</b>
<b>Ex-US Sites</b>	2	3	<b>173</b>
<b># Subjects</b>	1057	830	<b>6879</b>



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